

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)

Date of mailing (day/month/year)	10.04.2001
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Applicant's or agent's file reference 9904PC2/2221	IMPORTANT NOTIFICATION
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International application No. PCT/US00/00590	International filing date (day/month/year) 11/01/2000	Priority date (day/month/year) 11/01/1999
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Applicant SDGI HOLDINGS, INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 12 APR 2001

Applicant's or agent's file reference 9904PC2/2221		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/00590	International filing date (day/month/year) 11/01/2000	Priority date (day/month/year) 11/01/1999	
International Patent Classification (IPC) or national classification and IPC A61F2/44			
Applicant SDGI HOLDINGS, INC. et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 11 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 7 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input checked="" type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input checked="" type="checkbox"/> Certain defects in the international applicationVIII <input checked="" type="checkbox"/> Certain observations on the international application			
Date of submission of the demand 09/08/2000		Date of completion of this report 10.04.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Lega D'Incecco, A.M. Telephone No. +49 89 2399 2339 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/00590

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-3,6-12,15-25	as originally filed			
4,5	as received on	04/12/2000	with letter of	30/11/2000
13,14	as received on	02/03/2001	with letter of	28/02/2001

Claims, No.:

1-23	as originally filed			
24-37	as received on	04/12/2000	with letter of	30/11/2000

Drawings, sheets:

1/14-14/14	as originally filed
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2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence

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listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☒ the claims, Nos.: 38
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 6,28-35.

because:

- ☒ the said international application, or the said claims Nos. 6,28-35 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 6 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 28-35.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-5, 7-27,35-37
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-5,7-27,35-37
Industrial applicability (IA)	Yes:	Claims 1-5,7-27,35-37
	No:	Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/00590

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

III.

1. Claims 28 to 34 describe a method of promoting fusion bone growth in the space between adjacent vertebrae comprising steps (i.e. "placing the first elongated body in an intervertebral space between adjacent vertebrae") which clearly refer to a method of treatment of the human or animal body by surgery on which the International Preliminary Examining Authority is not required, under Article 34(4)(a)(i) and Rule 67.1(iv) PCT, to carry out an international preliminary examination.
2. These claims have also not been searched.
3. It should be noted that dependent claims 33 and 34 even if directed to a system, depend on a method claim and thus are considered as method claims.
4. The sole feature of apparatus claim 6 refers to a method step, and therefore this claim is not clear (art. 6 PCT).

Furthermore this method step ("is obtained as a transverse cut from the diaphysis of a long bone having a medullary canal") refers a method of obtaining a body of bone comprising the step which clearly refers to a method of treatment of the human or animal body by surgery on which the International Preliminary Examining Authority is not required, under Article 34(4)(a)(i) and Rule 67.1(iv) PCT, to carry out an international preliminary examination.

IV.

1. The application contains the independent apparatus claims 1, 21, 23 and 35. The inventions according to these independent claims are not so linked as to form a single general inventive concept for the following reasons:

There are no common features between these four independent claims and therefore there are no special technical features in the sense of Rule 13.2 PCT. Consequently, the application lacks unity.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/00590

3. The separate groups of invention are:

1. Claims 1-20, 21-22, 23-27: -

A first interbody fusion spacer comprising an elongated body with two arms defining an opening and having an end configured to form a region which an adjacent spacer can nest, the adjacent spacer, similar to the first and an interbody fusion implant system comprising the two fusion spacers.

2. Claims 35-37: -

A spacer insertion tool comprising a housing, a shaft and an occlusion member.

VIII.

1. The feature "the body of bone is obtained as a transverse cut from the diaphysis of a long bone having a medullary canal" of independent claim 21 refers to a method step, and therefore this claim is not clear (art. 6 PCT). Furthermore, this step clearly refers to a method of treatment of the human or animal body by surgery on which the International Preliminary Examining Authority is not required, under Article 34(4)(a)(i) and Rule 67.1(iv) PCT, to carry out an international preliminary examination.

Thus, this feature will not be considered in the examination.

It should, however be noted, that this feature is already known from document WO-A-98/55052 (D1) (cf. claim 10).

2. Independent claims 1 and 23 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved (see features "configured to form a region in within which an adjacent spacer can nest") which merely amounts to a statement of the underlying problem. The technical features necessary for achieving this result should have been added (see PCT Gazette, PCT Guidelines, Section IV, Chapter III-4.7).

The same applies to dependent claims 15, 17 and 26.

3. The vague and imprecise statement in the description on page 25 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see PCT Gazette, PCT Guidelines, Section IV, Chapter III-4.3a).
4. Independent claim 21 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

V.

1. The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1-5, 7-27 and 35-37 is not new in respect of the prior art as defined in the regulations (Rule 64(1)-(3) PCT) for the following reasons:

1.1 Independent claim 1:

Document WO-A-98/55052 (D1) discloses (cf. abstract; page 11, lines 1-24; page 12, lines 27-30; claims 1, 64 and 65; figures 4,5 and 11) an interbody fusion spacer (500,550) comprising: an elongated body (505) defining a chamber (530), the body (505) having first arm (520,580) and a second opposing arm (521,581), the arms (520,521,580,581) defining an opening (525), each of the arms (520,521,580,581) having an end (582,583) configured to form a region within which an adjacent spacer (500,550) can nest.

Even not explicitly described, a second spacer can nest at the end of the spacer disclosed in figure 11.

1.2 Independent claim 21:

Document WO-A-98/55052 (D1) discloses (cf. abstract; page 11, lines 1-24; page 12, lines 27-30; claims 1, 64 and 65; figures 4, 5 and 11) an interbody fusion spacer (500,550) comprising: an elongated body (505) of a bone having a longitudinal axis and defining a chamber (530) extending perpendicular to the longitudinal axis of the body (505), the body (505) having first arm (520,580) and a second opposing arm (521,581), the arms (520,521,580,581) defining an opening (525), each of the arms (520,521,580,581) having an end with a concave

surface (582,583) that forms a region within which an adjacent spacer (500,550) can nest.

Even not explicitly described, a second spacer can nest at the end of the spacer disclosed in figure 11.

1.3 Independent claim 23:

Document WO-A-98/55052 (D1) discloses (cf. abstract; page 11, lines 1-24; page 12, lines 27-30; claims 1, 64 and 65; figures 4,5 and 11) an interbody fusion implant system comprising a first interbody fusion spacer (500,550) having a first elongated body (505) of bone defining a first chamber (530), the body (505) having first arm (520,580) and a second opposing arm (521,581), the first and second arms (520,521,580,581) defining a first opening (525) in communication with the first chamber (530), each of the arms (520,521,580,581) having an end (582,583) configured to form a region within which an adjacent spacer (500,550) can nest: and a second elongated body (505) of bone and an outer surface (506), the second interbody fusion spacer (500,550) nestable within the first interbody fusion spacer (500,550).

Even not explicitly described, a second spacer can nest at the end of the spacer disclosed in figure 11.

1.4 Independent claim 35:

Document WO-A-98/55052 (D1) discloses (cf. page 29, line 16-page 31, line 12; claims 48-50; figures 24-31) a spacer insertion tool (800) comprising a housing (805) having proximal end (806) and an opposite distal end (807) and defining a passageway (810) between the proximal end (805) and the distal end (807); a shaft (815) having a first end (816) and an opposite second end (817), the shaft (815) being disposed within the passageway (810) with the first end (816) adjacent the distal end (807), the first end (816) defining a spacer engager (819); and an occlusion member (820) extendible from the distal end (807) of the housing (805) for blocking an opening (525) defined in the spacer (500,550) when the spacer engager (819) is engaged to the spacer (500,550), the occlusion member (820) having a plate (821) with an interior and exterior surface (825), at least one of the surfaces (825) of the plate (821) being curved, the occlusion

member (820) configured to span to a distal end (521,581) of the spacer.

1.5 Dependent claims:

- Claim 2 and 22: see D1, claim 2;
Claim 3: see D1, claim 6;
Claims 4, 5 and 18: see D1, claim 9
Claim 7: see D1, claim 4;
Claim 8, 16 and 20: see D1, page 12, lines 27-29;
Claim 9 and 27: see D1, claim 11;
Claim 10: see D1, claim 12;
Claims 11-14 : see D1, page 18, lines 15-29;
Claim 15 and 17: Even not explicitly described, the ends of the arms of the spacer disclosed in figure 11 of D1 have a surface configured to receive a convex surface of an adjacent spacer. Furthermore, each body disclosed in figure 11 has a first maximum outer diameter, and when nesting together two spacers, the spacer assembly will have a width lesser than the sum of the combined maximum diameters.
Claim 19,24 and 25: see D1, claim 1;
Claim 26: see D1, claim 1 and figure 11. Even not explicitly described, a second spacer can nest at the end of the spacer disclosed in figure 11.
Claim 36: see D1, claim 49;
Claim 37: see D1, claim 55.

VII.

1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
2. Independent claims 1, 21, 23 and 35 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

**INTERNATIONAL PRELIMINARY
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Independent claims 1, 21, 23 and 35 should therefore have been redrafted accordingly.

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The spacer engager 319 has any configuration which will engage a spacer. In some embodiments the spacer engager 319 includes a post for engaging a hole in the spacer. The post may have any configuration which will provide for mating engagement with a hole in a spacer. For example, the post may include an engager
5 319 which is threaded to matingly engage a threaded tool hole. Other embodiments and features may include a sharply pointed tip 319 as shown, or a hexagonal shaped tip. In each case, the engager is shaped and sized to mate engagingly with the tool hole of the spacer. In other embodiments, the spacer engaging means is a pair of prongs having opposite facing spacer engaging members for grasping an
10 outer surface of the spacer.

The spacer insertion tool 300 also includes an occlusion member 320 for blocking an opening defined in the spacer when the spacer engager 319 is engaged to the spacer. In a preferred embodiment, the occlusion member 320 is slideably engaged to the housing 305, and is extendible from the distal end 307 of the
15 housing 305 for blocking an opening in the spacer. The occlusion member 320 closes the mouth and channel defined in the spacer 100.

The tool 300 depicted also includes a handle portion 340. The handle portion includes means for slidingly moving the shaft 315 within the housing 305 and for rotating the shaft 315. In the embodiment shown, the means includes a
20 thumbwheel 341. In some embodiments, the handle portion 340 has a Hudson end attachment 342.

Referring now to Figures 14 and 15, shown are expanded views illustrating an inventive spacer 100 associated with the insertion tool 300 to form an assembly of the invention. As illustrated, insertion tool 300 has an occlusion member 320 having an
25 interior surface 324 which is convexly curved to complement the concave surfaces of ends 150 and 151 of arms 120 and 121, respectively, of spacer 100. Correspondingly, recess 308 of insertion tool 300 has a concave surface complementary to convexly curved surface 324 of occlusion member 320. Further, occlusion member 320 is of a

length and design sufficient to span to the distal end of the engaged spacer 100, as depicted in Figure 15. Occlusion member 320 can also have a beveled outer end, or an otherwise smoothed outer end, to facilitate rotary insertion.

Referring now to Figure 14, in one embodiment, the occlusion member 320 includes a plate 321 which defines a groove 322. A fastener 330 is engaged to a fastener bore 309 in the housing 305 and the groove 322 is disposed around the fastener 330. In this way, the plate 321 is slideable relative to the housing 305.

As shown, the housing 305 is preferably provided with a recess 308 which is defined to accept the occlusion member 320 without increasing the effective diameter of the device 300. The occlusion member is also adapted for the best fit with the spacer. For example, the interior surface 324 of the occlusion member would be curved to complement the concave end faces 150 and 151 for engagement. The plate 321 of the occlusion member 320 preferably includes a curved superior surface 325 which approximates and completes the minor diameter of the dowel 100 when the spacer engager 319 is engaged to the tool engaging hole and the occlusion member 320 is blocking the channel of the spacer 100. Preferably, the plate 321 and the arms 120 and 121 of the spacer 100 will be configured such that when the tool 300 is engaged to the spacer 100, the curved superior surface 325 will not increase the effective root diameter RD of the threaded outer surface of the spacer 100. This facilitates rotation and screw insertion of the spacer and occlusion member combination into an intervertebral space.

In preferred embodiments, as shown in Figures 14 and 15, the plate 321 defines a recess 326 surrounding a groove 322. A fastener 330 is engaged to a fastener bore 309 in the housing 305 and the groove 322 is disposed around the fastener 330. In this way, the plate 321 is slideable relative to the housing 305. The fastener 330 is preferably provided with a post 334, and a plate engaging means or head portion 335. The fastener 330 preferably includes an internal hex as shown for receiving a fastener driving

SUMMARY OF THE INVENTION

This invention provides spacers having an open chamber, tools for implanting the spacers and methods for making and using the spacers. The
5 spacers include an elongated body defining a chamber and having a first arm and a second arm. The arms define an opening in communication with the chamber. In one preferred embodiment, each of the arms has an end configured to form a region within which an adjacent spacer can nest, the ends desirably being substantially identical to each other. In a preferred form of the invention,
10 the arms each have an end with a concave surface extending to the outer edge or periphery of the spacer.

Spacers of the invention desirably have bodies composed of bone. In one aspect, the body is a dowel having a substantially C-shaped chamber and comprising an off-center bone plug obtained from the diaphysis of a long bone.

15 Another aspect of the invention provides interbody fusion implant systems. In one form of the invention, the systems includes two of the inventive spacers described above in nestable combination. In another form of the invention, the system includes one of the inventive spacers described above along with a second spacer nestable therewith. The second spacer may for
20 example have an elongated body and an outer surface, and may define a through-hole that preferably extends perpendicular to the longitudinal axis of the second body.

Tools for implanting spacers are also provided. The tools include spacer engaging means for engaging a spacer and occlusion means for blocking an
25 opening defined in the spacer. In one aspect the engaging means includes a shaft slidably disposed within a housing and having a threaded post for engaging a threaded tool hole in the spacer. In some embodiments, the occlusion means includes a plate extendible from the housing. In one specific embodiment the plate defines a groove which is disposed around a fastener
30 attached to the housing so that the plate is slideable relative to the housing. In

other preferred embodiments, the occlusion member has an interior and exterior surface wherein at least one of the surfaces is curved.

This invention also includes methods for obtaining an open bone dowel and methods for using the spacers of this invention. The methods of making a
5 dowel according to this invention include cutting an off-center plug from the diaphysis of a long bone to obtain a bone dowel having an open chamber. The dowel is machined to include desirable nestable surface features such as those described above, in addition to threads, grooves, instrument holes and the like. In still another aspect, the methods include chamfering the forward end of the
10 dowel.

The invention also concerns methods for using the spacers of this invention to promote fusion bone growth between adjacent vertebrae. In one form of the invention, the method for promoting fusion bone growth includes providing one of the spacers described above, preparing the adjacent vertebrae
15 to receive the elongated body of the spacer by, for example, making a cavity between two vertebrae to be fused and implanting or otherwise placing the elongated body into the intervertebral space. In some embodiments the chamber is packed with osteogenic material before the spacer is implanted. In other aspects of the invention, osteogenic material is packed into and around the
20 chamber through the mouth or channel after implantation.

The combination of the open-chambered spacers of this invention with the tools and methods of this invention provide a versatile spacer and implant systems. The spacers can be packed before or after implantation. This invention facilitates implanting a pair of open spacers close to each other in an
25 intervertebral space.

Accordingly, it is one object of this invention to provide nestable bone fusion spacers and methods for using the spacers in arthrodesis procedures.

Another object of this invention is to provide a dowel for vertebral fusions which has improved properties and versatility over standard dowels known in the
30 art.

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24. The system of claim 23, wherein said second elongated
5 body defines a through-hole.

25. The system of claim 24, wherein said second elongated
body has a longitudinal axis and said through-hole extends perpendicular
to said longitudinal axis.

10

26. The system of claim 23, wherein said second elongated body defines
a second chamber, said second body having a third arm and a fourth opposing arm,
said third and fourth arms defining a second opening in communication with said
second chamber, said second interbody fusion spacer nestable within said first
15 interbody fusion spacer.

27. The system of claim 26, said system further comprising an
osteogenic material disposed in at least one of said chambers of said spacers.

28. A method of promoting fusion bone growth in the space between
20 adjacent vertebrae, comprising:

(a) providing a first elongated body defining a first chamber, said
body having a first arm and a second opposing arm, said first and second arms
defining a first opening in communication with said first chamber, each of said first
25 and second arms having an end configured to form a region within which an
adjacent spacer can nest;

(b) preparing said adjacent vertebrae to receive the first
elongated body in an intervertebral space between adjacent vertebrae; and

(c) placing the first elongated body into the intervertebral space.

30

29. The method of claim 28, further comprising packing
osteogenic material into said first chamber of said first spacer prior to the
placing step.

30. The method of claim 28, further comprising implanting a
35 second spacer into the intervertebral space in a nested configuration
within ends of said first and second arms of said first spacer.

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31. The method of claim 28, further comprising implanting a
5 second one of said spacers into the intervertebral space after the placing
step and orienting the first and second spacers so that the channels of
the spacers face each other.

32. The method of claim 30, wherein said second interbody
10 fusion spacer is formed of bone.

33. The system of claim 32, wherein said second interbody
fusion spacer defines a through-hole.

34. The system of claim 33, wherein said through-hole extends
15 perpendicular to said longitudinal axis of said second elongated body.

35. A spacer insertion tool, comprising:
a housing having a proximal end and an opposite distal
20 end and defining a passageway between said proximal end and said
distal end;
a shaft having a first end and an opposite second end, said
shaft disposed within said passageway with said first end adjacent said
distal end, said first end defining a spacer engager; and
25 an occlusion member extendible from said distal end of
said housing for blocking an opening defined in the spacer when said
spacer engager is engaged to the spacer, said occlusion member having
a plate with an interior and exterior surface, at least one of said surfaces
of said plate being curved, said occlusion member configured to span to
30 a distal end of the spacer.

36. The tool of claim 35, further comprising a fastener attached
to said shaft and wherein said plate defines a groove, said groove
disposed around said fastener so that said plate is slidable relative to said
35 housing.

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37. The tool of claim 36, wherein said plate has a curved superior surface which approximates the outer surface of the spacer
5 when said spacer engaging means is engaged to the spacer and said occlusion member is blocking the opening of the spacer.

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 05 October 2000 (05.10.00)	
International application No. PCT/US00/00590	Applicant's or agent's file reference 9904PC2/2221
International filing date (day/month/year) 11 January 2000 (11.01.00)	Priority date (day/month/year) 11 January 1999 (11.01.99)
Applicant BOYD, Lawrence, M. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:08 August 2000 (08.08.00)☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Henrik Nyberg
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

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**NOTIFICATION CONCERNING
THE FILING OF AMENDMENTS OF THE CLAIMS**
(PCT Administrative Instructions, Section 417)

From the INTERNATIONAL BUREAU

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

RECEIVED

SEP 25 2000

Date of mailing (day/month/year) 12 September 2000 (12.09.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 9904PC2/2221	
International application No. PCT/US00/00590	International filing date (day/month/year) 11 January 2000 (11.01.00)
Applicant SDGI HOLDINGS, INC. et al	

1. The applicant is hereby notified that amendments to the claims under Article 19 were received by the International Bureau on:

07 September 2000 (07.09.00)

2. This date is within the time limit under Rule 46.1.

Consequently, the international publication of the international application will contain the amended claims according to Rule 48.2(f), (h) and (i).

3. The applicant is reminded that the international application (description, claims and drawings) may be amended during the international preliminary examination under Chapter II, according to Article 34, and in any case, before each of the designated Offices, according to Article 28 and Rule 52, or before each of the elected Offices, according to Article 41 and Rule 78.

<p align="center">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorised officer</p> <p align="center">Philippe Bécamel</p> <p>Telephone No.: (41-22) 338.83.38</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------

JAN 30 2001

Woodard, Emhardt, Naughton,
Moriarty & McNett

PCT

WRITTEN OPINION

(PCT Rule 66)

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

GANDY, Kenneth A.
WOODARD, EMHARDT, NAUGHTON,
MORIARTY & McNETT
Bank One Center/Tower, suite 3700
111 Monument Circle
INDIANAPOLIS, INDIANA 46204
ETATS-UNIS D'AMERIQUE

Date of mailing
(day/month/year)

19.01.2001

Applicant's or agent's file reference

9904PC2/2221

REPLY DUE

within 2 month(s)
from the above date of mailing

International application No.

PCT/US00/00590

International filing date (day/month/year)

11/01/2000

Priority date (day/month/year)

11/01/1999

International Patent Classification (IPC) or both national classification and IPC

A61F2/44

Applicant

SDGI HOLDINGS, INC. et al.

ENTERED
3-19-01

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain document cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 11/05/2001.

Name and mailing address of the international preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer / Examiner

Lega D'Incecco, A.M.

Formalities officer (incl. extension of time limits)

Ertl, L

Telephone No. +49 89 2399 7447



I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-3,6-25	as originally filed		
4,5	as received on	04/12/2000 with letter of	30/11/2000

Claims, No.:

1-23	as originally filed		
24-37	as received on	04/12/2000 with letter of	30/11/2000

Drawings, sheets:

1/14-14/14	as originally filed
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2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☒ the claims, Nos.: 38
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 6,29-35,

because:

- ☒ the said international application, or the said claims Nos. 6,29-35 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 6 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 29-35.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees, the applicant has:

WRITTEN OPINION

International application No. PCT/US00/00590

- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:
3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement
- | | | |
|-------------------------------|--------|------------------|
| Novelty (N) | Claims | 1-5, 7-27, 35-37 |
| Inventive step (IS) | Claims | |
| Industrial applicability (IA) | Claims | |

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

III.

1. Claims 28 to 34 describe a method of promoting fusion bone growth in the space between adjacent vertebrae comprising steps (i.e. "placing the first elongated body in an intervertebral space between adjacent vertebrae") which clearly refer to a method of treatment of the human or animal body by surgery on which the International Preliminary Examining Authority is not required, under Article 34(4)(a)(i) and Rule 67.1(iv) PCT, to carry out an international preliminary examination.
2. These claims have also not been searched.
3. It should be noted that dependent claims 33 and 34 even if directed to a system, depend on a method claim and thus are considered as method claims.
4. The sole feature of apparatus claim 6 refers to a method step, and therefore this claim is not clear (art. 6 PCT).

Furthermore this method step ("is obtained as a transverse cut from the diaphysis of a long bone having a medullary canal") refers a method of obtaining a body of bone comprising the step which clearly refers to a method of treatment of the human or animal body by surgery on which the International Preliminary Examining Authority is not required, under Article 34(4)(a)(i) and Rule 67.1(iv) PCT, to carry out an international preliminary examination.

IV.

1. The application contains the independent apparatus claims 1, 21, 23 and 35. The inventions according to these independent claims are not so linked as to form a single general inventive concept for the following reasons:

There are no common features between these four independent claims and therefore there are no special technical features in the sense of Rule 13.2 PCT. Consequently, the application lacks unity.

3. The separate groups of invention are:

1. Claims 1-20, 21-22, 23-27: -

A first interbody fusion spacer comprising an elongated body with two arms defining an opening and having an end configured to form a region which an adjacent spacer can nest, the adjacent spacer, similar to the first and an interbody fusion implant system comprising the two fusion spacers.

2. Claims 35-37: -

A spacer insertion tool comprising a housing, a shaft and an occlusion member.

VIII.

1. The feature "the body of bone is obtained as a transverse cut from the diaphysis of a long bone having a medullary canal" of independent claim 21 refers to a method step, and therefore this claim is not clear (art. 6 PCT). Furthermore, this step clearly refers to a method of treatment of the human or animal body by surgery on which the International Preliminary Examining Authority is not required, under Article 34(4)(a)(i) and Rule 67.1(iv) PCT, to carry out an international preliminary examination.

Thus, this feature will not be considered in the examination.

It should, however be noted, that this feature is already known from document WO-A-98/55052 (D1) (cf. claim 10).

2. Independent claims 1 and 23 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved (see features "configured to form a region in within which an adjacent spacer can nest") which merely amounts to a statement of the underlying problem. The technical features necessary for achieving this result should be added (see PCT Gazette, PCT Guidelines, Section IV, Chapter III-4.7).

The same applies to dependent claims 15, 17 and 26.

3. The vague and imprecise statement in the description on page 25 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see PCT Gazette, PCT Guidelines, Section IV, Chapter III-4.3a).
4. Independent claim 21 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).

V.

1. The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1-5, 7-27 and 35-37 is not new in respect of the prior art as defined in the regulations (Rule 64(1)-(3) PCT) for the following reasons:

1.1 Independent claim 1:

Document WO-A-98/55052 (D1) discloses (cf. abstract; page 11, lines 1-24; page 12, lines 27-30; claims 1, 64 and 65; figures 4, 5 and 11) an interbody fusion spacer (500,550) comprising: an elongated body (505) defining a chamber (530), the body (505) having first arm (520,580) and a second opposing arm (521,581), the arms (520,521,580,581) defining an opening (525), each of the arms (520,521,580,581) having an end (582,583) configured to form a region within which an adjacent spacer (500,550) can nest.

Even not explicitly described, a second spacer can nest at the end of the spacer disclosed in figure 11.

1.2 Independent claim 21:

Document WO-A-98/55052 (D1) discloses (cf. abstract; page 11, lines 1-24; page 12, lines 27-30; claims 1, 64 and 65; figures 4, 5 and 11) an interbody fusion spacer (500,550) comprising: an elongated body (505) of a bone having a longitudinal axis and defining a chamber (530) extending perpendicular to the longitudinal axis of the body (505), the body (505) having first arm (520,580) and a second opposing arm (521,581), the arms (520,521,580,581) defining an

opening (525), each of the arms (520,521,580,581) having an end with a concave surface (582,583) that forms a region within which an adjacent spacer (500,550) can nest.

Even not explicitly described, a second spacer can nest at the end of the spacer disclosed in figure 11.

1.3 Independent claim 23:

Document WO-A-98/55052 (D1) discloses (cf. abstract; page 11, lines 1-24; page 12, lines 27-30; claims 1, 64 and 65; figures 4,5 and 11) an interbody fusion implant system comprising a first interbody fusion spacer (500,550) having a first elongated body (505) of bone defining a first chamber (530), the body (505) having first arm (520,580) and a second opposing arm (521,581), the first and second arms (520,521,580,581) defining a first opening (525) in communication with the first chamber (530), each of the arms (520,521,580,581) having an end (582,583) configured to form a region within which an adjacent spacer (500,550) can nest: and a second elongated body (505) of bone and an outer surface (506), the second interbody fusion spacer (500,550) nestable within the first interbody fusion spacer (500,550).

Even not explicitly described, a second spacer can nest at the end of the spacer disclosed in figure 11.

1.4 Independent claim 35:

Document WO-A-98/55052 (D1) discloses (cf. page 29, line 16-page 31, line 12; claims 48-50; figures 24-31) a spacer insertion tool (800) comprising a housing (805) having proximal end (806) and an opposite distal end (807) and defining a passageway (810) between the proximal end (805) and the distal end (807); a shaft (815) having a first end (816) and an opposite second end (817), the shaft (815) being disposed within the passageway (810) with the first end (816) adjacent the distal end (807), the first end (816) defining a spacer engager (819); and an occlusion member (820) extendible from the distal end (807) of the housing (805) for blocking an opening (525) defined in the spacer (500,550) when the spacer engager (819) is engaged to the spacer (500,550), the occlusion member (820) having a plate (821) with an interior and exterior surface (825), at

least one of the surfaces (825) of the plate (821) being curved, the occlusion member (820) configured to span to a distal end (521,581) of the spacer.

1.5 Dependent claims:

- Claim 2 and 22: see D1, claim 2;
Claim 3: see D1, claim 6;
Claims 4, 5 and 18: see D1, claim 9
Claim 7: see D1, claim 4;
Claim 8, 16 and 20: see D1, page 12, lines 27-29;
Claim 9 and 27: see D1, claim 11;
Claim 10: see D1, claim 12;
Claims 11-14 : see D1, page 18, lines 15-29;
Claim 15 and 17: Even not explicitly described, the ends of the arms of the spacer disclosed in figure 11 of D1 have a surface configured to receive a convex surface of an adjacent spacer. Furthermore, each body disclosed in figure 11 has a first maximum outer diameter, and when nesting together two spacers, the spacer assembly will have a width lesser than the sum of the combined maximum diameters.

Claim 19,24 and 25: see D1, claim 1;
Claim 26: see D1, claim 1 and figure 11. Even not explicitly described, a second spacer can nest at the end of the spacer disclosed in figure 11.

Claim 36: see D1, claim 49;
Claim 37: see D1, claim 55.

VII.

1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
2. Independent claims 1, 21, 23 and 35 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in a

preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

Independent claims 1, 21, 23 and 35 should therefore be redrafted accordingly.

If, however, the applicant is of the opinion that the two-part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of claims 1, 21, 23 and 35 are known from document D1 (see PCT Gazette, PCT Guidelines, Section IV, Chapter III-2.3a).

3. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 34(2)(b) PCT).
4. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

PCT INTERNATIONAL APPLICATION TRANSMITTAL LETTER

11 January 2000

REGARDING THE INTERNATIONAL APPLICATION OF
SDGI HOLDINGS, INC., et al.DOCKET OR REFERENCE NUMBER
9904PC2/2221

ENTITLED

TRUNCATED OPEN INTERVERTEBRAL SPACERS

Certification under 37 CFR 1.10 (if applicable)

EL016470205US

11 January 2000

"Express Mail" mailing number

Date of Deposit

I hereby certify that this application is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10, on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

LINDA S.W. CONRAD

(Typed or printed name of person
mailing application)

Linda S.W. Conrad

(Signature of person mailing
application)

To the United States Receiving Office (RO/US):

Accompanying this transmittal letter is the above-identified International application, including a completed Request form (PCT/RO/101). Please process the application according to the provisions of the Patent Cooperation Treaty.

The following requests are made of the RO/US:

1. ☒ PREPARATION AND TRANSMITTAL OF CERTIFIED COPY OF PRIORITY DOCUMENTS—Please prepare and transmit to the International Bureau a certified copy of the United States origin priority documents identified in Box VI of the Request form (37 CFR 1.451).

To cover the cost of copy preparation and certification (37 CFR 1.19(a)(2) and (b)(1)),

☒ a (check) (money order) in the amount of \$ 15.00 included is attached to this transmittal letter.

☐ the RO/US is hereby authorized to charge the following deposit account no.: _____

2. ☒ CHOICE OF INTERNATIONAL SEARCHING AUTHORITY—It is requested that the International Search be performed by the following International Searching Authority:

☐ United States Patent and Trademark Office (ISA/US)

☒ European Patent Office (ISA/EP)

The appropriate Search fee for the above-named Authority is indicated on the Fee Calculation Sheet (PCT/RO/101 Annex).

3. ☐ SUPPLEMENTAL SEARCH FEES (ONLY WHEN ISA/US CONDUCTS THE INTERNATIONAL SEARCH.)—Please charge any Supplemental Search fees that may be required by the United States International Searching Authority (ISA/US) to deposit account no.: _____

I understand that this authorization is subject to my oral confirmation thereof in each instance and that it in no way limits my right to submit a protest against payment of the Supplemental Search fees, but is merely an administrative aid to assure that the ISA/US may timely complete the Search Report.

NOTE: SUPPLEMENTAL SEARCH FEES FOR ISA/EP ARE PAYABLE DIRECTLY TO THE EUROPEAN PATENT OFFICE

4. ☒ DISCLOSURE INFORMATION—In order to assist in screening the accompanying International application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied:

A. ☐ There is no prior filed application relating to this invention.

B. ☒ There is a prior application, serial number 60/115,388 filed on 11 January 1999 (11.01.99) which contains subject matter that is

1. ☐ substantially identical to that of the accompanying International application.

2. ☐ less than that of the accompanying International application. The additional subject matter of the International application appears on page(s) and line(s) _____

3. ☒ more than that of the accompanying International application.

C. ☐ Disclosure information cannot be covered by the language of Points 4A or 4B above due to the involvement of several prior applications or for other reasons. A separate sheet on which the disclosure information is explained is attached to this transmittal letter.

5. ☒ REQUEST FOR FOREIGN TRANSMITTAL LICENSE—According to the provisions of 35 U.S.C. 184 and 37 CFR 5.11, a license to transmit the accompanying International application to foreign agencies or international authorities is hereby requested.

SIGNER IS THE



APPLICANT



COMMON REPRESENTATIVE



(ATTORNEY) (AGENT)

REG NO

#33,386

NAME OF SIGNER (typed)

Kenneth A. GANDY

SIGNATURE

Kenneth A. Gandy

This sheet is not part of and does not count as a sheet of the international application.

PCT

FEE CALCULATION SHEET Annex to the Request

For receiving Office use only

International application No.

Applicant's or agent's
file reference

9904 PC2/2221

Date stamp of the receiving Office

Applicant

SDGI HOLDINGS, INC., et al.

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE 240 T
2. SEARCH FEE 1005 S

International search to be carried out by EP
(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains 51 sheets.

first 30 sheets 427 b1
21 x 10 = 210 b2
remaining sheets additional amount

Add amounts entered at b1 and b2 and enter total at B 637 B

Designation Fees

The international application contains 83 designations.

8 x 92 = 736 D
number of designation fees amount of designation fee
payable (maximum 10)

Add amounts entered at B and D and enter total at I 1373 I

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT (if applicable) 15 P

5. TOTAL FEES PAYABLE 2633

Add amounts entered at T, S, I and P, and enter total in the TOTAL box

TOTAL

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

- ☒ authorization to charge deposit account (see below) ☐ bank draft ☐ coupons
☒ cheque ☐ cash ☐ other (specify):
☐ postal money order ☐ revenue stamps

DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may not be available at all receiving Offices)

The RO/ US ☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☒ (this check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit) is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

23-3030

Deposit Account No.

11 January 2002
Date (day/month/year)

Signature Kenneth A. Gandy, #33 386

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) 9904PC2/2221

Box No. I TITLE OF INVENTION

TRUNCATED OPEN INTERVERTEBRAL SPACERS

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

SDGI HOLDINGS, INC.
300 Delaware Avenue, Suite 508
Wilmington, Delaware 19801 US

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State (that is, country) of nationality:

US

State (that is, country) of residence:

US

This person is applicant
for the purposes of:

☐

all designated
States

☒

all designated States except
the United States of America

☐

the United States
of America only

☐

the States indicated in
the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

BOYD, Lawrence M.
688 S. McLean Boulevard
Memphis, Tennessee 38104 US

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box
is marked, do not fill in below.)

State (that is, country) of nationality:

US

State (that is, country) of residence:

US

This person is applicant
for the purposes of:

☐

all designated
States

☐

all designated States except
the United States of America

☒

the United States
of America only

☐

the States indicated in
the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☒

agent

☐

common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

GANDY, Kenneth A.
WOODARD, EMHARDT, NAUGHTON, MORIARTY & MCNETT
Bank One Center/Tower, Suite 3700
111 Monument Circle
Indianapolis, Indiana 46204 US
SEE CONTINUATION TO BOX NO. IV ON SHEET NO. 4

Telephone No.

317-634-3456

Facsimile No.

317-637-7561

Teleprinter No.

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

BURKUS, J. Kenneth
7162 Williams Hill Road
Columbus, Georgia 31904 US

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

US

State (that is, country) of residence:

US

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

DORCHAK, John D.
P.O. Box 400
Midland, Georgia 31820 US

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

US

State (that is, country) of residence:

US

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes: at least one must be marked):

Regional Patent

- ☒ **AP** ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA** Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> AE United Arab Emirates | <input checked="" type="checkbox"/> LR Liberia |
| <input checked="" type="checkbox"/> AL Albania | <input checked="" type="checkbox"/> LS Lesotho |
| <input checked="" type="checkbox"/> AM Armenia | <input checked="" type="checkbox"/> LT Lithuania |
| <input checked="" type="checkbox"/> AT Austria | <input checked="" type="checkbox"/> LU Luxembourg |
| <input checked="" type="checkbox"/> AU Australia | <input checked="" type="checkbox"/> LV Latvia |
| <input checked="" type="checkbox"/> AZ Azerbaijan | <input checked="" type="checkbox"/> MA Morocco |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina | <input checked="" type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> BG Bulgaria | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input checked="" type="checkbox"/> BR Brazil | <input checked="" type="checkbox"/> MN Mongolia |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> MW Malawi |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CR Costa Rica | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> CZ Czech Republic | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> DE Germany | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> DM Dominica | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> EE Estonia | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> FI Finland | <input checked="" type="checkbox"/> SK Slovakia |
| <input checked="" type="checkbox"/> GB United Kingdom | <input checked="" type="checkbox"/> SL Sierra Leone |
| <input checked="" type="checkbox"/> GD Grenada | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GE Georgia | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> GH Ghana | <input checked="" type="checkbox"/> TR Turkey |
| <input checked="" type="checkbox"/> GM Gambia | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> TZ United Republic of Tanzania |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> ID Indonesia | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> IN India | |
| <input checked="" type="checkbox"/> IS Iceland | |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> YU Yugoslavia |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> ZA South Africa |
| | <input checked="" type="checkbox"/> ZW Zimbabwe |
| <input checked="" type="checkbox"/> KR Republic of Korea | |
| <input checked="" type="checkbox"/> KZ Kazakhstan | |
| <input checked="" type="checkbox"/> LC Saint Lucia | |
| <input checked="" type="checkbox"/> LK Sri Lanka | |

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

☐

☐

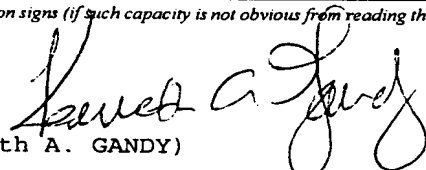
Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)

Supplemental Box *If the Supplemental Box is not used, this sheet should not be included in the request.*

1. If, in any of the Boxes, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:
- (i) if more than two persons are involved as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;
 - (ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;
 - (iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;
 - (iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;
 - (v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "continuation" or "continuation-in-part": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;
 - (vi) if, in Box No. VI, there are more than three earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI;
 - (vii) if, in Box No. VI, the earlier application is an ARIPO application: in such case, write "Continuation of Box No. VI", specify the number of the item corresponding to that earlier application and indicate at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed.
2. If, with regard to the precautionary designation statement contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.
3. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerning non-prejudicial disclosures or exceptions to lack of novelty: in such case, write "Statement concerning non-prejudicial disclosures or exceptions to lack of novelty" and furnish that statement below.

Continuation to Box No. IV Agent

WOODARD, Harold R.; EMHARDT, C. David; NAUGHTON, Joseph A., Jr.; MORIARTY, John V.; McNETT, John C.; HENRY, Thomas Q.; DURLACHER, James M.; REEVES, Charles R.; WAGNER, Vincent O.; ZLATOS, Steve; BEREVESKOS, Spiro; BAHRET, William F.; BROWNING, Clifford W.; FRISK, R. Randall; LUEDERS, Daniel J.; GANDY, Kenneth A.; THOMAS, Timothy N.; SISSELMAN, Kerry P.; JONES, Kurt N.; ALLIE, John H.; BANTA, Holiday W.; COLE, Troy J.; PAYNTER, L. Scott; LOWES, J. Andrew; MEYER, Charles J.; HARRIS, Darrin Wesley; SCHANTZ, Matthew R.; COY, Gregory B.; HIDAY, Lisa A.; DANILUCK, John V.; BROWN, Christopher A.; SCHWARTZ, Jason J.; USHER, Arthur J. IV; COLLIER, Douglas A.; MYERS, James B. Jr.; STEVENS, Scott J., and ROWE, James L., all of Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, Indiana 46204 United States of America

Box No. VI PRIORITY CLAIM					<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:			
		national application: country	regional application: regional Office	international application: receiving Office	
item (1) (11.01.99) 11 January 1999	60/115,388	US			
item (2)					
item (3)					
<input checked="" type="checkbox"/> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1)					
<small>* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.</small>					
Box No. VII INTERNATIONAL SEARCHING AUTHORITY					
Choice of International Searching Authority (ISA) <small>(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):</small>		Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):			
ISA/ EP		Date (day/month/year)	Number	Country (or regional Office)	
		11 January 1999	60/115,388	US	
Box No. VIII CHECK LIST; LANGUAGE OF FILING					
This international application contains the following number of sheets: request : 5 description (excluding sequence listing part) : 25 claims : 6 abstract : 1 drawings : 14 sequence listing part of description : n/a Total number of sheets : 51		This international application is accompanied by the item(s) marked below: 1. <input checked="" type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input checked="" type="checkbox"/> other (specify): Transmittal Letter (dup)			
Figure of the drawings which should accompany the abstract: 1		Language of filing of the international application: English			
Box No. IX SIGNATURE OF APPLICANT OR AGENT					
<small>Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).</small>					
Applicant(s): SDGI HOLDINGS, INC. BOYD, Lawrence M. BURKUS, J. Kenneth DORCHAK, John D.		Agent:  (Kenneth A. GANDY)			

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA /	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.

For International Bureau use only
Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

RECEIVED

APR 13 2000

Woodard, Emhardt, Naughton,
Moriarty & McNett

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 30 March 2000 (30.03.00)	
Applicant's or agent's file reference 9904PC2/2221	IMPORTANT NOTIFICATION
International application No. PCT/US00/00590	International filing date (day/month/year) 11 January 2000 (11.01.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 11 January 1999 (11.01.99)
Applicant SDGI HOLDINGS, INC. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
11 Janu 1999 (11.01.99)	60/115,388	US	17 Marc 2000 (17.03.00)

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. (41-22) 740.14.35</p>	<p>Authorized officer</p> <p>Carlos Naranjo</p> <p>Telephone No. (41-22) 338.83.38</p>
-----------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------

RECEIVED

PATENT COOPERATION TREATY

OCT 23 2000

Notified to: Woodard, Emhardt, Naughton,
Moriarty & McNett

PCT

From the INTERNATIONAL BUREAU

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

INFORMATION CONCERNING ELECTED OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)

Date of mailing (day/month/year) 05 October 2000 (05.10.00)		
Applicant's or agent's file reference 9904PC2/2221		IMPORTANT INFORMATION
International application No. PCT/US00/00590	International filing date (day/month/year) 11 January 2000 (11.01.00)	
Priority date (day/month/year) 11 January 1999 (11.01.99)		
Applicant SDGI HOLDINGS, INC. et al		

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

AP : GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW

EP : AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE

National : AU, BG, CA, CN, CZ, DE, IL, JP, KP, KR, MN, NO, NZ, PL, RO, RU, SE, SK, US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

EA : AM, AZ, BY, KG, KZ, MD, RU, TJ, TM

OA : BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG

National : AE, AL, AM, AT, AZ, BA, BB, BR, BY, CH, CR, CU, DK, DM, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IN, IS, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MW, MX, PT, SD,
SG, SI, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW

3. The applicant is reminded that he must enter the "national phase" before the expiration of 30 months from the priority date before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing, if prescribed, a translation of the international application (Article 39(1)(a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3)(b) and Rule 74.1).

Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide.

The entry into the European regional phase is postponed until 31 months from the priority date for all States designated for the purposes of obtaining a European patent.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer: Henrik Nyberg Telephone No. (41-22) 338.83.38
--------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------



PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

RECEIVED

APR 05 2001

Woodard, Emhardt, Naughton,
Moriarty & McNett

Date of mailing (day/month/year) 28 March 2001 (28.03.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 9904PC2/2221	
International application No. PCT/US00/00590	International filing date (day/month/year) 11 January 2000 (11.01.00)

1. The following indications appeared on record concerning:



the applicant



the inventor



the agent



the common representative

Name and Address	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:



the person



the name



the address



the nationality



the residence

Name and Address ESTES, Bradley, T. 5169 Tarrytown Drive Memphis, TN 38117 United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

The person identified in Box 2 should be added to the records as applicant and inventor
for the purposes of the United States of America only.

4. A copy of this notification has been sent to:



the receiving Office



the International Searching Authority



the International Preliminary Examining Authority



the designated Offices concerned



the elected Offices concerned



other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Yolaine CUSSAC Telephone No.: (41-22) 338.83.38
-----------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 28 March 2001 (28.03.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 9904PC2/2221	
International application No. PCT/US00/00590	International filing date (day/month/year) 11 January 2000 (11.01.00)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address RAY, Eddie, F., III 1781 Fernhall Cove Collierville, TN 38017 United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

The person identified in Box 2 should be added to the records as applicant and inventor for the purposes of the United States of America only.

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Yolaine CUSSAC Telephone No.: (41-22) 338.83.38
------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------